METHOD OF FORMING CATHETER DISTAL TIP

Technical Field

The invention relates generally to elongate medical devices and more particularly to catheters and methods of forming catheter distal tips.

Background

Reinforcing layers such as reinforcing braid layers can provide thin-walled catheters with desired resistance to kinking while retaining desirable flexibility. Some reinforcing braids, such as tempered or high tensile stainless steel braids, can be susceptible to braid wire flaring in which unrestrained ends of the braid bend outward. Various techniques have been proposed for dealing with braid wire flaring, including the use of heat treatment processes on the braid, braid constraints and adhesives. Nevertheless, a need remains for improved methods of producing catheters having reinforcing braids while preventing or substantially preventing braid wire flaring without thickening the top layer or heat-treating the reinforcing braid material. A need also remains for a braid-reinforced catheter that has a well-bonded soft distal tip without use of adhesives.

Summary

The invention is directed to catheters such as guide catheters that can include a reinforcing braid layer. Guide catheters can include distal tips such as atraumatic distal tips in which the reinforcing braid layer does not extend into the distal tip.

Accordingly, an example embodiment of the invention can be found in a method of forming a catheter. A braid layer is provided and a first polymer segment is secured over the braid layer. The first polymer segment can be positioned proximal of a distal

end of the braid layer. The braid layer can be cut through at a cutting position that is proximate a distal end of the first polymer segment and the braid layer distal of the cutting position can be removed. A second polymer segment, that extends over the first polymer segment and that extends distally of the cutting position can be secured over the braid layer.

Another example embodiment of the invention can be found in a guide catheter that has a braid layer and an outer polymer layer and that is produced using a preferred process. A first polymer segment can be positioned over the braid layer and can be secured such that it is proximal of a distal end of the braid layer. The braid layer can be cut through at a cutting position that is proximate a distal end of the first polymer segment, and a portion of the braid layer that is distal of the cutting position can be removed. A second polymer segment that forms the outer polymer layer can be secured over the braid layer. The second polymer segment can extend over the first polymer segment and can extend distally of the cutting position.

Another example embodiment of the invention can be found in a guide catheter that includes an inner lubricious layer and a reinforcing braid layer that each extend proximally from a position proximal of a distal end of the catheter. An outer polymeric layer can extend proximally from the distal end of the catheter. A braid securement segment can extend proximally from a position proximal of the distal end of the catheter.

The braid securement segment can have a melting point that is lower than a melting point of the inner lubricious layer, but higher than a melting point of the outer polymeric layer. The braid securement segment can be melted into the braid layer, thereby preventing braid flaring during processing.

Brief Description of the Figures

Figure 1 is a plan view of a catheter in accordance with an embodiment of the invention;

Figure 2 is a cross-sectional view of the catheter of Figure 1 taken along line 2-2;

Figure 3 is a partially sectioned view of the catheter of Figure 1 illustrating an example braid pattern;

Figure 4 is a partially sectioned view of the catheter of Figure 1;

Figure 5 is a partial sectional view of a distal portion of a catheter shaft showing a liner, reinforcing braid and braid securement segment in accordance with an embodiment of the invention;

Figure 6 is a partial section view of an alternative embodiment of the distal portion of a catheter shaft of Figure 5;

Figure 7 is a partial section view of the distal catheter shaft portion of Figure 5 showing the addition of a heat shrink tube;

Figure 8 is a partial section view of the distal catheter shaft portion of Figure 7 after applying heat to the heat shrink tube covered assembly;

Figure 9 is a partial section view of the distal catheter shaft portion of Figure 8 after removing the heat shrink tube;

Figure 10 is a partial section view of the distal catheter shaft portion of Figure 9 after cutting through the braid and liner at the distal end of the braid securement segment;

Figure 11 is a partial section view of the distal catheter shaft portion of Figure 10 after positioning segments of the outer polymer layer and a heat shrink tube;

Figure 12 is a partial section view of the distal catheter shaft portion of Figure 11 after applying heat to the heat shrink tube;

Figure 13 is a partial section view of the distal catheter shaft portion of Figure 12 illustrating the completed distal tip;

Figure 14 is a cross-section view of Figure 13 taken along line 14-14; and

Figure 15 is a cross-section view of Figure 13 taken along line 15-15.

Detailed Description

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The

drawings, which are not necessarily to scale, depict illustrative embodiments of the claimed invention.

Figure 1 is a plan view of a catheter 10 in accordance with an embodiment of the present invention. The catheter 10 can be any of a variety of different catheters. In some embodiments, the catheter 10 can be an intravascular catheter. Examples of intravascular catheters include balloon catheters, atherectomy catheters, drug delivery catheters, diagnostic catheters and guide catheters. The intravascular catheter 10 can be sized in accordance with its intended use. The catheter 10 can have a length that is in the range of about 100 to 150 centimeters and can have any useful diameter. As illustrated, Figure 1 portrays a guide catheter, but the invention is not limited to such. Except as described herein, the intravascular catheter 10 can be manufactured using conventional techniques.

In the illustrated embodiment, the intravascular catheter 10 includes an elongate shaft 12 that has a proximal end 14 and a distal end 16. A hub and strain relief assembly 18 can be connected to the proximal end 14 of the elongate shaft 12. The hub and strain relief assembly 18 includes a main body portion 20, a pair of flanges 22 designed to improve gripping and a strain relief 24 that is intended to reduce kinking. The hub and strain relief assembly 18 can be of conventional design and can be attached using conventional techniques. It is also recognized that alternative hub designs can be incorporated into embodiments of the present invention.

The elongate shaft 12 can include one or more shaft segments having varying degrees of flexibility. As illustrated, the elongate shaft 12 includes a first shaft segment 26, a second shaft segment 28 and a third shaft segment 30. In some embodiments, the elongate shaft 12 can include fewer shaft segments or only one shaft segment or can

include more than three segments, depending on the flexibility requirements of a particular application.

Figure 2 is a cross-sectional view of the elongate shaft 12, taken along the line 2-2 of Figure 1, while Figure 4 is a cutaway view of the elongate shaft 12. The proximal portions of the elongate shaft 12, as illustrated, include an outer layer 34 and an inner layer 36, and can include a reinforcement layer 38 that is positioned between the inner layer 36 and the outer layer 34. The inner layer 36 defines a lumen 40 that extends through the elongate shaft 12. In some embodiments, the inner layer 36 can be omitted. The distal portion 32 of the elongate shaft 12 will be discussed in greater detail hereinafter.

Each of the shaft segments 26, 28, 30 can have a similar construction. In particular, each of the shaft segments 26, 28, 30 can include an inner layer 36 and a reinforcing layer 38 that is the same for or continuous through each of the shaft segments 26, 28, 30 and an outer layer 34 that becomes more flexible in the shaft segments 26, 28, 30 closest to the distal end 16 of the catheter 10. For example, the proximal shaft segment 26 can have an outer layer that is formed from a polymer having a hardness of 72D (Durometer), the intermediate shaft segment 28 can have an outer layer having a hardness of 68D and the distal shaft segment 30 can have an outer layer having a hardness of 46D.

Each of the shaft segments 26, 28, 30 can be sized in accordance with the intended function of the resulting catheter 10. For example, the shaft segment 26 can have a length of about 35 inches, the shaft segment 28 can have a length in the range of

about 2 to 3 inches and the shaft segment 30 can have a length in the range of about 1 to 1.25 inches.

The shaft segments 26, 28, 30 can be formed of any suitable material such as a polymeric material. Examples of suitable polymer material include any of a broad variety of polymers generally known for use as polymer sleeves. In some embodiments, the polymer material used is a thermoplastic polymer material. Some examples of some suitable materials include polyurethane, elastomeric polyamides, block polyamide/ethers, block polyethers/esters, silicones, and co-polymers. One preferred polymer is a polyurethane (PUR) and polyoxymethylene (POM or Delrin) blend.

In some embodiments, the inner layer 36 can be a single piece uniform material extending over the length of the shaft 12 and can define a lumen 40 that can run the entire length of the elongate shaft 12 and that is in fluid communication with a lumen (not illustrated) extending through the hub assembly 18. The lumen 40 defined by the inner layer 36 can provide passage to a variety of different medical devices or fluids, and thus the inner layer 36 can be manufactured from or include a lubricious material to reduce friction within the lumen 40. Examples of suitable materials include polytetrafluoroethylene (PTFE). The inner layer 36 can be dimensioned to define a lumen 40 having an appropriate inner diameter to accommodate its intended use. In some embodiments, the inner layer 36 can define a lumen 40 having a diameter of about 0.058 inches and can have a wall thickness of about 0.001 inches. A lubricious coating over the lumen wall of inner layer 36 can also be included.

In some embodiments, the outer layer 34 can include a portion made from a thermoplastic polymer such as a co-polyester thermoplastic polymer such as that

available commercially under the ARNITEL® name. The use of an ARNITEL® polymer is described in detail below. The outer layer 34 can have an inner diameter that is about equal to the outer diameter of the inner layer 36. The outer layer 34 can have an inner diameter that is slightly greater than the outer diameter of the inner layer 36 to accommodate the thickness of the reinforcing braid layer 38. In some embodiments, the outer layer 34 can have an inner diameter in the range of about 0.0600 to about 0.0618 inches and an outer diameter in the range of about 0.0675 to about 0.0690 inches.

In some embodiments, the outer layer 34, or portions thereof, can include, or be filled with, radiopaque material to make the outer layer 34, or portions thereof, more visible when using certain imaging techniques, for example, fluoroscopy techniques. Any suitable radiopaque material known in the art can be used. Some examples include precious metals, tungsten, barium subcarbonate powder, and the like, and mixtures thereof. In some embodiments, the polymer can include different sections having different amounts of loading with radiopaque material. For example, the outer layer 34 can include a distal section having a higher level of radiopaque material loading, and a proximal section having a correspondingly lower level of loading.

A reinforcing braid layer 38 can be positioned between the inner layer 36 and the outer layer 34. With reference to Figure 3, the reinforcing braid layer 38 can be formed of any suitable material, including metals and metal alloys. In some embodiments, the reinforcing braid layer 38 can include a metal wire braid formed of stainless steel, tungsten, gold, titanium, silver, copper, platinum, molybdenum or iridium. The reinforcing braid layer 38 can also be formed from non-metallic material such as KEVLAR® (poly paraphenylene terephthalamide) fibers, LCP (liquid crystal polymer)

fibers or glass fibers. In some embodiments, the reinforcing braid layer 38 can be formed of a high tensile stainless steel.

In at least some embodiments, portions or all of the reinforcing braid layer 38 can include a radiopaque material. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like.

In some embodiments, a degree of MRI compatibility can be imparted. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make the reinforcing braid layer 38, or other portions thereof, in a manner that would impart a degree of MRI compatibility. For example, the reinforcing braid layer 38, or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts, which are gaps in the image. Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The reinforcing braid layer 38, or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, Elgiloy, MP35N, nitinol, and the like, and others.

In some embodiments, the reinforcing braid layer 38 can be formed of a plurality of individual fibers 42. The individual fibers 42 can be flat or round or other shapes (D-shaped, triangle, etc.) in cross-section and can be woven together in a variety of patterns. As illustrated, the fibers 42 are woven together in a three-over-three pattern, while any other patterns such as a four-over-four pattern or even a five-over five pattern or a two

over four pattern can also be used. In particular, the fibers 42 can be formed of wire having a round cross-section and a diameter of about 0.001 inches.

An intravascular catheter 10 can optionally include a coating layer such as a lubricious coating layer over part or all of the catheter 10. Suitable lubricious polymers are well known in the art and can include hydrophilic polymers such as polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility. Certain hydrophobic coatings such as PTFE, silicone coatings, etc., can also be utilized.

The distal portion 32 of the elongate shaft 12 is described, for example, in Figures 5 through 12, which illustrate an exemplary method of forming the distal portion 32, as well as Figures 13-15, which illustrate the finished distal portion 32 of the elongate shaft 12.

In an example method of forming the distal portion 32, Figures 5 and 6 show an optional inner liner 44 positioned over a mandrel 46. In some embodiments, the inner liner 44 can represent a distal portion of the inner liner 36 discussed with respect to the more proximal portions of the elongate shaft 12. A reinforcing braid layer 48 having a distal end 56 (Figure 6) has been positioned over the inner liner 44. In some embodiments, the reinforcing braid layer 48 can represent a distal portion of the reinforcing braid layer 38 discussed with respect to the more proximal portions of the elongate shaft.

A braid securement segment 50 can be positioned over the reinforcing braid layer 48. The braid securement segment 50 can have a distal end 52 and a proximal end 54, and the braid securement segment 50 can be positioned such that the reinforcing braid layer 48 extends distally beyond the distal end 52 of the braid securement segment 50.

The inner layer 44 can be formed of any suitable polymer as discussed above. In some embodiments, the inner layer 44 can be formed of a fluoropolymer such as polytetrafluoroethylene (PTFE). The reinforcing braid layer 48 can be formed of any suitable reinforcing material. In some embodiments, the reinforcing braid layer 48 can be formed of high tensile stainless steel.

The braid securement segment 50 can be formed of any suitable polymer as discussed previously. It can be advantageous for the braid securement segment 50 to be formed of a polymer that has a melting point that is less than that of the inner layer 44. In some embodiments, the braid securement segment 50 can be formed of a polyether-ester polymer having a melting point of greater than about 400° F. ARNITEL PL380, which is a suitable example of such a polymer, has a melting point of about 413°F.

The braid securement segment 50 can be dimensioned as appropriate for the particular catheter being formed. In some embodiments, the braid securement segment 50 can have a length that is in the range of about 0.1 to about 40 inches and a wall thickness that is in the range of about 0.0005 to about 0.006 inches.

In positioning and subsequently securing the braid securement segment 50, it can be advantageous to prevent the distal end 56 of the braid securement segment 50 from flaring. In some embodiments, as illustrated for example in Figure 5, this can be accomplished at least in part by extending the reinforcing braid layer 48 distally of where

the braid securement segment 50 is being attached. It has been found that when a reinforcing braid made from a high tensile material such as high tensile stainless steel flares, typically only the ends of the braid will flare. Thus, it can be beneficial but not necessary to extend the reinforcing braid layer 48 a distance of about 0.1 inches or more distally beyond the braid securement segment 50.

In some embodiments, as illustrated for example in Figure 6, it can be advantageous to secure the distal end 56 of the reinforcing braid layer 48 at a position distal of the braid securement segment 50. This can be accomplished using any suitable mechanical means of securement, such as twisting individual elements of the distal end 56 of the reinforcing braid layer 48 together, or soldering or otherwise adhering the individual elements of the distal end 56 together.

Once the braid securement segment 50 has been positioned over the reinforcing braid layer 48, it can be secured thereon using any suitable method, preferably heat and pressure. In some embodiments, as illustrated for example in Figures 7 and 8, a heat shrink tube 58 can be positioned over the braid securement segment 50. Figure 7 shows the heat shrink tube 58 prior to applying sufficient heat to shrink the heat tube 58, while Figure 8 shows the heat shrink tube 58 after sufficient heat has been applied to at least partially melt the braid securement segment 50 into or to conform with the reinforcing braid layer 48.

The heat shrink tube 58 can be formed of any suitable heat shrink polymer known in the art. In some embodiments, it can be beneficial to use a heat shrink polymer that has a melting point that is above that of the braid securement segment 50. In some particular embodiments, the heat shrink tube 58 can be formed of a fluoropolymer such

as a perfluoro (ethylene-propylene) copolymer having a melting point of at least about 500° F.

Figure 9 illustrates the distal portion 32 after the heat shrink tube 58 has been removed. As illustrated, the braid securement segment 50 has been at least partially melted into or conformed to the reinforcing braid layer 48. As a result, the braid securement segment 50 can at least substantially prevent flaring during subsequent processing steps.

Processing continues as illustrated in Figure 10, in which the inner liner 44 (if present) and the reinforcing braid layer 48 are cut through at a cutting position 60. Cutting can be accomplished using any suitable method, including mechanical shearing or ablative techniques such as a laser. In some embodiments, the cutting position 60 can be proximate the distal end 52 of the braid securement segment 50. The portions 61 of the inner liner 44 and the reinforcing braid layer 48 that extend distally of the cutting position 60 can be removed.

Figures 11-12 illustrate a particular method of forming the outer layer 62, shown for example in Figure 13. The outer layer 62 can be formed of any suitable polymer. In one embodiment, the outer layer 62 is formed of a polymer that has a melting point that is below that of the braid securement segment 50. As a result, thermal processing of the outer layer 62 (as described hereinafter) will have little or no effect on the braid securement segment 50, and thus the reinforcing braid layer will exhibit substantially no flaring.

The outer layer 62 can be formed from a single polymer tube, or a plurality of individual segments. In some illustrated embodiments, the outer layer 62 can be formed

from a proximal segment 64 that is configured to overlay the reinforcing layer 48, an intermediate segment 66 that is configured to overlay the braid securement segment 50, and a distal segment 68 that is configured to form a distal tip. Each of the proximal segment 64, the intermediate segment 66 and the distal segment 68 can be formed from the same material, or each can be different. Alternatively, segments of polymer materials may be blended with other polymers or different materials.

In some embodiments, each of the proximal segment 64, the intermediate segment 66 and the distal segment 68 can be formed of the same material, but of differing mechanical characteristics. In some embodiments, the outer layer 62 can be formed of a polymer that has a melting point that is below about 400 °F, and in particular embodiments, the outer layer 62 can be formed of a polymer such as an acetal resin/polyurethane blend that has a melting point of about 350° F. A preferred polymer is a polyoxymethylene and polyurethane blend.

Each of the proximal segment 64, the intermediate segment 66 and the distal tip 68 can be secured using any suitable method, preferably heat and pressure. In some embodiments, as illustrated for example in Figures 11 and 12, a heat shrink tube 70 can be used. In some embodiments, sufficient heat is applied to melt the proximal segment 64, the intermediate segment 66 and the distal segment 68 without melting or excessively softening the braid reinforcement segment 50.

Figure 11 shows the heat shrink tube 70 prior to applying sufficient heat to shrink the heat tube 70 while Figure 12 shows the heat shrink tube 70 after sufficient heat has been applied. The heat shrink tube 70 can be formed of any suitable material, such as those discussed with respect to the heat shrink tube 58.

In some embodiments, as illustrated for example in Figures 12-15, the proximal segment 64, the intermediate segment 66 and the distal segment 68 are all formed of the same polymer and can form a continuous outer layer 62 after heat shrinking. In particular, Figure 13 shows a distal portion 32 having a continuous outer layer 62. The outer layer 62 includes a distal tip 64 that is free of any reinforcing braid layer 48 or inner layer 44 and thus can provide a suitable level of flexibility.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.